K131072

3. 510(k) SUMMARY

JUL 09 2013

510(k) Owner's Name:	Coloplast A/S
Address:	Holtedam 1 3050 Humlebaek, Denmark
Phone/Fax/Email:	Office: (612) 302-4987 Mobile: (612) 968-9567 Fax: (612) 287-4138 Email: usbes@coloplast.com
Name of Contact Person:	Brian E. Schmidt Regulatory Affairs Manager
Address/Contact:	1601 West River Road N Minneapolis, MN 55411

Date Prepared:	April 15th, 2013
Trade Name:	Orchestra® Hydrophilic Guidewire
Common Name:	Hydrophilic guidewire
Classification Name:	Endoscopic Guidewire, Gastroenterology-Urology
Product code:	OCY

Description of the Device:

The Orchestra® Hydrophilic Guide Wire is a guidewire consisting of a metallic core wire with a polymer coating. A hydrophilic coating is applied over the radiopaque polymer jacket. The guidewire is supplied sterile and non-pyrogenic.

Intended Use of the Device:

The Orchestra® Hydrophilic guidewire is intended to facilitate the placement of devices through the urinary tract during endourological procedures.

Predicate Device:

The Orchestra® Hydrophilic Guidewires are substantially equivalent in performance, indication, design and materials to Radifocus® Guidewire M from Terumo Medical Corp, cleared under Premarket notification # K923607.

Summary and Conclusions from the Nonclinical Tests Submitted:

Product performance testing comparing the subject device to the predicate device included the following tests/analysis: visual control, dimensional test, tensile test on guidewire, flexibility test for guidewire, X-rays opacity test, guidewire fracture test, guidewire flexibility damage resistance test, oxidation test, friction test.

Conclusion

Based on the indications for use, design, technical charcteristics, safety, and successfully completed performance testing, the Orchestra® Hydrophilic Guidewires are substantially equivalent to Radifocus® Guidewire M from Terumo Medical Corp, cleared under Premarket notification # K923607.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 9, 2013

Coloplast Corp.
% Mr. Brian E. Schmidt
Regulatory Affairs Manager
1601 West River Road N
MINNEAPOLIS MN 55411

Re: K131072
Trade/Device Name: Orchestra hydrophilic guidewire standard angled, orchestra hydrophilic guidewire straight stiff, orchestra hydrophilic
Regulation Number: 21 CFR 876.1500
Regulation Name: Hydrophilic Guidewire
Regulatory Class: Class II
Product Code: OCY
Dated: April 15, 2013
Received: April 17, 2013

Dear Mr. Schmidt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Elaine H. Blyskun -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K131072

Device Name: **Orchestra® Hydrophilic Guidewire**

Indications for Use:

The hydrophilic guidewire is intended to facilitate the placement of devices through the urinary tract during endourologic procedures.

Prescription Use ____X___ Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elaine H. Blyskun -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K131072